

DEROYAL INDUSTRIES, INC.
ELECTROSURGICAL CAUTERY PENCIL

K 961647

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED

OCT - 8 1996

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc. TELEPHONE: (423) 938-7828
ADDRESS: 200 DeBusk Lane CONTACT: Debra F. Manning
Powell, TN 37849 DATE OF PREPARATION: April 22, 1996

DEVICE NAMES

NAME: DeRoyal Industries, Inc. Electrosurgical Cautery Pencil
COMMON/USUAL NAME: Cautery Pencil
CLASSIFICATION NAME (if known): Electrosurgical Cutting & Coagulation Device and Accessories (79 GEI)

PREDICATE OR LEGALLY MARKETING DEVICES

DeBusk Technology Corporation

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Electrosurgical Cautery Pencil functions in the same manner as predicate devices in that it is intended to be used in electrosurgical procedures to remove tissue and control bleeding. The device can be used for both cutting and coagulating.

Device Design/Materials Used/Physical Properties: The DeRoyal Industries, Inc. Electrosurgical Cautery Pencil is made of materials commonly used for their purpose. The concept of use is that the device is intended to remove tissue and control bleeding by use of high frequency electrical current.

DEVICE INTENDED USE

The DeRoyal Cautery Pencil is indicated for use whenever an electrosurgical procedure requires the removal of tissue or the control of bleeding by either cutting or coagulation.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	DeBusk Technology Device	Rationale
Length of Pencil Body	6.0"	6.0"	
Length of Cable	10'0"	10'0"	
Material of Outer Cable Insulation	PVC	PVC	
Method of Manufacturing of Tip	Stamped and formed from sheet of stainless steel	Stamped and formed from sheet of stainless steel	
Tip Coating	Titanium Nitride	None	Provides a non-toxic, anti-stick, lubricated surface.